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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,945	03/26/2004	Nicholas P. Harberd	620-298	6433

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,945	HARBERD ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 0104*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 55-104 are pending and are examined.

Specification

At pages 18 and 25, ---SEQ ID NO: 4-- should be inserted after "DVAQKLEQLE" in each occurrence.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Claim Objections

Claims 58-61 and 67 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 58 does not further limit parent claim 55 because the recited property is inherent. Claims 59-61 broaden the scope of parent claim 55, therefore, do not further limit parent claim. Claim 67 broadens the scope of parent claim 64, therefore does not further limit parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polynucleotide sequences encoding SEQ ID NO: 1, 7, 5, and 8, and polynucleotide sequences encoding Rht wheat comprising SEQ ID NO: 104 and 103, and transgenic plants or plant parts expressing said polypeptides, does not reasonably provide enablement for isolated polynucleotide sequences from any sources encoding polypeptides having at least 80%, 90%, and 95% sequence similarity to SEQ ID NO: 1, polynucleotide sequences that hybridize to SEQ ID NO: 14 and that do not contain comprising SEQ ID NO:105, and nucleic acids comprising nucleotide sequences complementary to a sequence of at least 50 contiguous nucleotides of a polynucleotide encoding a polypeptide having 80% sequence similarity to SEQ ID NO: 1 or said polypeptides with at least 10 or 16 residues similarity or identity with SEQ ID NO:104 and still retaining plant growth inhibition activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

Applicant broadly claims isolated polynucleotides from any source encoding polypeptides with at least 80%, 90%, and 95% similarity to SEQ ID NO: 1, said polypeptides comprising at least 10 or 16 residues that show similarity with the residue in the corresponding position in SEQ ID NO: 104, said polynucleotide encoding a polypeptide with 80% similarity hybridizes to SEQ ID NO: 14; and wherein said polypeptides retain plant growth inhibition activity. The claims are also drawn to isolated polynucleotides encoding polypeptides having at least 80% similarity with SEQ ID NO: 1 and with one or more amino acids deleted, and polynucleotides encoding SEQ ID NO: 8 or 5 and with one or more amino acids deleted; and

nucleic acid comprising a sequence complementary to a sequence of at least 50 contiguous bases of a polynucleotide encoding a polypeptide having at least 80% similarity to SEQ ID NO: 1.

The specification teaches isolated polynucleotide sequences from wheat, maize, and rice encoding SEQ ID NO: 1, 7, 5, and 8, and polynucleotides encoding Rht polypeptide from wheat comprising SEQ ID NO: 104 and 103. The specification discloses that SEQ ID NO:102-106 are the domains responsible for plant growth inhibition activity. The specification, however, does not disclose or provide any guidance for the obtention and use of all the polynucleotides of the claims. The specification does not provide guidance for any modifications to the disclosed sequences that resulted a polypeptide having 80% sequence similarity to SEQ ID NO: 1 or 7 and retaining growth inhibition activity. Applicant has not taught polynucleotides other those encoding SEQ ID NO: 1, 7, 5 and 8, and polypeptides thereof with the sequence of SEQ ID NO: 102, 103, 104, and 106 deleted, said polypeptides retaining the GA unresponsive activity. Applicant has not taught that every 50 contiguous nucleotides of the disclosed polynucleotides are sufficient to encode functional polypeptides having the desired GA unresponsive or responsive growth activity. One skilled in the art would have to test

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The prior art as exemplified by Lazar et al. (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1252 (U)) and Broun et al. (Science, 13 November 1998, Vol. 282, pp. 131-133 (W)), teach unpredictability in protein function when one or more amino acids in that protein is modified. Lazar et al teaches a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (Title). Broun et al teaches as few as four amino acid substitutions can change an oleate 12-desaturase activity (Abstract). One would not expect that modifications that involve conservative substitution of amino acids are likely to change, while substitutions that are less conservative are unlikely to affect protein function. The nucleic acids encoding the polypeptides (original and modified) disclosed by either Lazar et al or Broun et al, would hybridize to each under the high stringent conditions as recited in claims 61 and 67, and the polypeptides would share more than 95% similarity, but they still differ in function. Therefore, given the lack of guidance; the unpredictability inherent in protein function as evidenced by Lazar et al and Broun et al; the state of the prior art, as discussed above, one skilled in the art would not be able to practice the claimed invention without undue experimentations. Therefore, hybridizing property or structural similarity of nucleic acid/protein sequences cannot be used to predict protein function.

Furthermore, while the specification provides guidance on conserved regions required for GA-responsive activity of the polypeptides of SEQ ID NO: 1, 5, and 8, the specification does not provide guidance regarding deletions of "anyone or more amino acid deletion" that retain the polypeptide function. It is unpredictable how the "anyone or more amino acid deletion" will affect the stated polypeptide function. In addition, the polynucleotides encoding SEQ ID NO: 1, 5, and 8, all from related species, and are not representative of the broad scope of the polynucleotide

sequences from all sources. One would have to test all possible sequences having the structural property as recited in the claims to determine, through the myriad of transgenic plants transformed with each of said polynucleotide, which will encode a polypeptide having the desired function. These tests are considered excessive and undue.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55-104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6, 762,

346. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the application are drawn to polynucleotides encoding SEQ ID NO: 1, 7, 5, and 8 and variants thereof with the sequence of SEQ ID NO: 104 or 106 deleted, hybridizing sequences, and host cells and plants transformed with said polynucleotide. The claims of the instant application are broader in scope, therefore, encompass than the claims of the patent. For example, polynucleotide encoding a polypeptide having t least 80%, 90%, and 95% similarity to SEQ ID NO: 1, and transgenic plants comprising them of the application encompass a polynucleotide encoding SEQ ID NO: 1 and transgenic plants comprising it of the patent. Therefore, the invention claimed in the application is obvious over the invention claimed in the patent.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/20/06

MAI

MEDINA A. IBRAHIM
PRIMARY EXAMINER